AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 1382

Introduced by Assembly Member Nakanishi

February 22, 2005

An act to add Sections 111723 and 111785.3 to the Health and Safety Code, relating to contact lenses. An act to amend Sections 2541.3, 2541.6, and 2543 of the Business and Professions Code, relating to prescription lenses.

LEGISLATIVE COUNSEL'S DIGEST

AB 1382, as amended, Nakanishi. Tinted noncorrective (plano) contact lenses: adulterated and misbranded *Prescription* lenses.

Existing law requires the State Department of Health Services, the State Board of Optometry, and the Division of Licensing and Division of Medical Quality of the Medical Board of California to prepare and adopt quality standards and adopt regulations relating to prescription ophthalmic devices, including, but not limited to, contact lenses. With respect to furnishing contact lenses that do not have a prescriptive power for vision correction, also known as plano contact lenses, existing law requires a prescription. A violation of these regulations is a misdemeanor.

The existing Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of food, drugs, and cosmetics. The law prohibits a person from manufacturing, selling, delivering, holding, offering for sale, or receiving in commerce any cosmetic that is adulterated, and prohibits a person from adulterating any cosmetic. The law also prohibits a person from manufacturing or selling any cosmetic that is misbranded. A violation of these provisions is punishable as a misdemeanor.

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This bill would provide that plano tinted contact lenses intended to change the appearance of the normal eye in decorative fashion and marketed or offered for sale in this state are considered cosmetics and are adulterated if they are distributed without the involvement of a physician and surgeon or optometrist as provided under existing provisions regulating prescription lenses. The bill would provide that these cosmetic plano tinted contact lenses are misbranded if their labeling fails to make 4 disclosures.

Because a violation of the requirements prescribed by the bill would be a crime, this bill would impose a state-mandated local program.

Existing law provides that it is a deceptive marketing practice for any licensed physician and surgeon, licensed optometrist, or registered dispensing optician to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.

This bill would expand the scope of this provision by making it a deceptive marketing practice for any person to do these acts.

Because a violation of regulations related to contact lenses is a crime, this bill would expand the scope of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 2541.3 of the Business and Professions
- 2 Code is amended to read:
- 3 2541.3. (a) The State Department of Health Services, the
- 4 State Board of Optometry and the Division of Licensing and
- 5 Division of Medical Quality of the Medical Board of California
- 6 shall prepare and adopt quality standards and adopt regulations
- 7 relating to prescription ophthalmic devices, including, but not
- 8 limited to, lenses, frames, and contact lenses. Regulations

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adopted subsequent to those in effect on July 1, 1976, shall become operative July 1, 1978. In promulgating such these rules and regulations, the department and the boards shall adopt the current standards of the American National Standards Institute regarding ophthalmic materials. Nothing in this section shall prohibit the department and the boards from jointly adopting subsequent standards which that are equivalent or more stringent than the current standards of the American National Standards Institute regarding ophthalmic materials.

No

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(b) No individual or group—which that deals with prescription ophthalmic devices, including, but not limited to, distributors, dispensers, manufacturers, laboratories, optometrists, or ophthalmologists shall sell, dispense, or furnish any prescription ophthalmic device—which that does not meet the minimum standards set by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California.

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(c) Any violation of the regulations adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California pursuant to this section shall be a misdemeanor.

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(d) Any optometrist, ophthalmologist, or dispensing optician who violates the regulations adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California pursuant to this section shall be subject to disciplinary action by his or her licensing board.

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(e) The State Board of Optometry or the Division of Licensing and Division of Medical Quality of the Medical Board of California may send any prescription ophthalmic device to the State Department of Health Services for testing as to whether or not-such the device meets established standards adopted pursuant to this section, which testing shall take precedence over any other prescription ophthalmic device testing being conducted by the department. The department may conduct-such the testing in its

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own facilities or may contract with any other facility to conduct such the testing.

- 3 SEC. 2. Section 2541.6 of the Business and Professions Code 4 is amended to read:
 - 2541.6. Effective January 1, 1977, no No prescription ophthalmic device which that does not meet the standards adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California under Section 2541.3 shall be purchased with state funds.
 - SEC. 3. Section 2543 of the Business and Professions Code is amended to read:
 - 2543. (a) Except as provided in the Nonresident Contact Lens Seller Registration Act (Chapter 5.45 (commencing with Section 2546), the right to dispense, sell or furnish prescription lenses at retail or to the person named in a prescription is limited exclusively to licensed physicians and surgeons, licensed optometrists, and registered dispensing opticians as provided in this division. This section shall not be construed to affect licensing requirements pursuant to Section 111615 of the Health and Safety Code.
 - (b) It shall be considered a deceptive marketing practice for any—licensed physician and surgeon, licensed optometrist, or registered dispensing optician person to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.
 - SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
 - SECTION 1. Section 111723 is added to the Health and Safety Code, to read:
 - 111723. (a) (1) For purposes of this part, plano tinted contact lenses intended to change the appearance of the normal

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eye in decorative fashion and marketed or offered for sale in this state are considered cosmetics.

- (2) For purposes of this section, "plano" means noncorrective or zero prescriptive power.
- (b) A plano tinted contact lens described in subdivision (a) is adulterated as described in Section 111670 if the lens is distributed without the involvement of a physician and surgeon or optometrist as provided in Chapter 5.4 (commencing with Section 2540) of Division 2 of the Business and Professions Code.
- SEC. 2. Section 111785.3 is added to the Health and Safety Code, to read:
 - 111785.3. Cosmetic plano tinted contact lenses described in Section 111723 are misbranded if their labeling fails to disclose all of the following:
 - (a) That adverse consequences, such as serious damage or injury to the eye and eye problems, including corneal ulcers and ultimate loss of vision, may result even if the lenses are used under labeled, customary, or usual conditions.
 - (b) That some persons are not suitable for contact lens wear due to the presence of ocular or systemic health conditions.
 - (e) That lens wear by a person who is not a suitable candidate poses a greater risk of serious damage or injury to that person's eye.
 - (d) That first-time lens users should consult a physician and surgeon or optometrist as provided in Chapter 5.4 (commencing with Section 2540) of Division 2 of the Business and Professions Code to determine their suitability for lens wear prior to use.
- SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, climinates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.